



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 26 2000

Sidney M. Wolfe, M.D.  
Public Citizen's Health Research Group  
1600 20<sup>th</sup> Street, N.W.  
Washington, DC 20009-1001

Re: Docket No. 00P-1084

Dear Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on March 13, 2000. Your petition requests that the Agency revise the professional product labeling for the thiazolidinediones, or "glitazone" diabetes drugs.

FDA has been unable to reach a decision on your petition because it raises complex scientific issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

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